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Intra-patient comparison of reduced-dose model-based iterative reconstruction with standard-dose adaptive statistical iterative reconstruction in the CT diagnosis and follow-up of urolithiasis

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Short title:

Use of MBIR in CT scans for urinary stones

Abstract

Objectives

To evaluate the accuracy of reduced-dose CT scans reconstructed using a new generation of model based iterative reconstruction (MBIR) in the imaging of urinary tract stone disease, compared with a standard-dose CT using 30% adaptive statistical iterative reconstruction.

Methods

This single institution prospective study recruited 125 patients presenting either with acute renal colic or for follow up of known urinary tract stones. They underwent two immediately consecutive scans, one at standard dose settings and one at the lowest dose (highest noise index) the scanner would allow. The reduced-dose scans were reconstructed using both ASIR 30% and MBIR algorithms and reviewed independently by two radiologists. Objective and subjective image quality measures as well as diagnostic data were obtained.

Results

The reduced-dose MBIR scan was 100% concordant with the reference-standard for the assessment of ureteric stones. It was extremely accurate at identifying calculi of 3mm and above. The algorithm allowed a dose reduction of 58% without any loss of scan quality.

Conclusions

A reduced-dose CT scan using MBIR is accurate in acute imaging for renal colic symptoms and for urolithiasis follow up and allows a significant reduction in dose.

Key Points

MBIR allows reduced CT dose with similar diagnostic accuracy

MBIR outperforms ASIR when used for the reconstruction of reduced-dose scans

MBIR can be used to accurately assess stones 3mm and above

Key Words

Computed tomography

Urolithiasis

Renal colic

Radiation dosage

Kidney

Abbreviations

ASIR Adaptive statistical iterative reconstruction

MBIR Model-based iterative reconstruction

Introduction

Clinical radiology services are of increasing importance in most diagnostic pathways. There is an exponential increase in cross-sectional imaging, with a rise of 29% in the number of CT scans performed in England over the three years between 2012/13 and 2015 alone[1]. In the UK, whilst the use of ionising radiation for medical imaging has remained relatively constant, the proportion resultant from CT has increased greatly[2]. In the US, dose per head, and the amount attributable to CT have both increased[2]. Ionising radiation is thought to increase the risk of cancer incidence and cancer mortality even at low doses[3] and the cancer incidence associated with multiple exposures could potentially be high[4]. This is especially relevant in urinary stone disease which often requires frequent follow-up, recommended at yearly intervals by the American Urological Association[5].

Iterative reconstruction (IR) algorithms offer a significant advantage over the use of filtered back projection (FBP) by allowing for a lower dose without compromising quality[6]. The first generation uses a blend of IR and FBP. The latest generation of IR has seen the development of a model-based purely iterative technique. These allow a reduction in noise whilst increasing spatial resolution and have been shown to be useful both in phantom studies and in the clinical setting. Since 2012, several papers have demonstrated its potential diagnostic utility in (amongst other areas) whole body[7], chest [8–10], abdominal and pelvic[11–13] and cardiac CT[14] imaging. Pilot[15, 16] and prospective[17] studies have specifically investigated the role of MBIR in the imaging of urinary tract calculi.

A CT scan of the kidneys, ureters and bladder (KUB) is well established as the imaging investigation of choice for suspected renal colic or for the follow up of stone disease[18–21]. The use of low-dose protocols for these scans is well established. Images are ‘noisier’ but diagnostic confidence is maintained[22, 23] due to the high inherent contrast between the calcific stones and the background soft tissue. The aim of this study was to evaluate the accuracy of scans for the primary investigation and follow up of urolithiasis, comparing model-based iterative reconstruction (MBIR) acquired at a very low dose with a standard care adaptive statistical iterative reconstruction (ASIR) algorithm.

Materials and Methods

Study Population

Local and regional ethics committee approval was obtained for this single centre prospective study, and 125 patients were recruited having given signed informed consent. Recruitment occurred between October 2014 and March 2016.

Any patient above the age of 18 having an unenhanced CT KUB scan for the purpose of diagnosis or follow-up of urinary tract stone disease was eligible. Demographic, morphologic and clinical data was recorded for each participant (specifically, body mass index (BMI), the presence and side of colic symptoms, results of bedside urine dipstick analysis and also the number of previous occurrences).

Imaging Protocol

All the examinations were performed on a single 64-row helical CT scanner (Discovery CT 750HD, GE Healthcare, Milwaukee, Wisconsin, USA). They were performed without intravenous contrast. The scan protocol began with our institution's standard-dose acquisition followed immediately in the same breath hold by a reduced-dose acquisition at a noise index (NI) of 85 (the highest possible NI). Both images were acquired over identical segments.

The scan parameters used are described in Table 1. They had been initially tested using phantoms and by reference to earlier work in the department[16] where the MBIR algorithm had been applied retrospectively to CT KUB scans.

Reconstruction Algorithms

Three sets of images were reconstructed. The standard-dose scan was reconstructed solely with the 30% ASIR algorithm that is well established in our department, to act as a reference standard. The reduced-dose scan was reconstructed twice: once with ASIR 30% and once with MBIR. The scans were reconstructed on a GE workstation to produce anonymised axial datasets with a slice thickness of 1.25mm.

Image Quality Assessment

Subjective Assessment

The images were assessed qualitatively by two cross-sectional radiologists, one consultant and one fellow (C.R. and S.T., with 24 and 4 years' experience of reporting abdominal CT respectively). A score between 1 and 5 was given for the image (Electronic Table 1). A score of 3 or above was deemed acceptable for diagnostic purposes.

Objective Assessment

Noise in the reconstructed series was assessed quantitatively by a post-exam fellow (ST) who positioned the regions of interest (ROIs) on each patient's CT scan in a standard location (the subcutaneous fat anterior to the bladder) on three contiguous slices. The size was in each case identical (15mm diameter i.e. 177mm^2). The positioning[16, 24–27] and size[17, 26, 27] of the ROI were in line with techniques used in previous similar research. The ROI was automatically populated within all reconstructed scans in an identical location by GE proprietary software. From the 3 contiguous slices, mean attenuation and standard deviation (as a measure of noise) in Hounsfield Units (HUs) from each reconstructed scan were tabulated. Noise was defined as the mean of the standard deviations and compared between the 3 series. We controlled for dose by establishing a figure of merit (FOM) for each study derived from the noise (N) and the effective dose (ED) using the following formula: $\text{FOM} = 1/(\text{N}^2 \cdot \text{ED})$ [28].

Assessment of Diagnostic Accuracy

For each patient, three series of images were reconstructed, as described above. The purpose of the ASIR 30% reconstruction of the reduced-dose scan was to establish whether simply dropping the dose and using our standard reconstruction would provide sufficiently diagnostic results without the need for MBIR. The scans were anonymised and independently reviewed in batches of 25 by the two aforementioned cross-sectional radiologists (C.R. and S.T.). Each reconstruction was treated as a single study and given a random number within the batch of 25. This ensured that reporters were

blind to the reconstruction algorithm to avoid bias. This did leave some potential for recall bias if two studies from the same patient were closely numbered. This was minimised by blinding reporters to clinical and laboratory information. Reporters did not feel that recall bias was a problem.

The primary endpoint was taken to be the presence of a ureteric stone; features of obstructive uropathy (presence of renal collecting system or ureteric dilatation and perinephric or periureteric stranding) were also recorded. The reference standard was the result of the normal standard of care scan (standard-dose, ASIR 30%), as interpreted by that same reader. Many of our scans were performed for follow up of known urinary tract calculi, so we also recorded the number and size of all calculi on each scan. We used a secondary endpoint of the ability of the scan to accurately identify renal calculi of various sizes, again using the normal standard of care scan as the reference standard. We performed further analysis considering each CT scan as a diagnostic test for correctly characterising the renal stone disease in each patient (i.e. identifying every stone, not identifying any false positives). We used various size thresholds in order to assess, for example the overall accuracy for assessing renal stones of 1mm and above in size, 2mm and above in size and so on.

Assessment of Dose Delivered

The dose delivered was available as a separate series within the examination data. The volume CT dose index (CTDI_{vol}), dose-length product (DLP) and size-specific dose estimate (SSDE) were calculated for each patient based on a 32 cm polymethyl methacrylate phantom using the technique specified by the American Association of Physicists in Medicine task group 204[29] (i.e. the maximum abdominal AP and lateral dimensions were measured manually from the CT radiographs). The effective dose in millisieverts (mSv) was calculated using the tissue-weighting factor for the abdomen and pelvis (k coefficient) of 0.015[30] derived from tissue weighting factors from the International Commission on Radiological Protection publication 103[31]. The following equation was used:

$$\text{effective dose} = k \times \text{DLP}.$$

Statistical Analysis

We conducted statistical analysis using STATA version 14.0 (StataCorp, College Station, Texas). A *P*-value of <0.05 was considered statistically significant. Qualitative variables were presented as numbers and related percentages and quantitative variables were presented as means $\pm$ standard deviation and 95% confidence intervals. Where applicable, the area under the curve (AUC) for the receiver operating characteristic (ROC) with a cut-point of >0 to define disease status has been provided. The qualitative and quantitative assessments of image quality were compared by using Wilcoxon signed rank test, paired t-test and Kruskal-Wallis as appropriate. Inter- and intraobserver diagnostic concordance was examined using the κ test. The reference standard was the standard-dose scan reconstructed using ASIR 30%. The reduced-dose scans using different reconstruction algorithms were treated as index tests.

Sample size was determined on the basis of 90% power and a type I error of 5%. A null value of 0.4 was set, and a κ value of 0.7 determined as the level at which the kappa was significantly different from the null. Based on a predicted low positive primary outcome rate in this mixed in- and outpatient study, 109 patients were needed.

Results

We included 125 patients with a mean age of 54.4 years $\pm$ 16.6 (range 18-88 years). There were 71 men and 54 women. Patient body habitus varied considerably. Weights ranged from 45 to 146 kg (mean weight, 82.7 kg $\pm$ 18.6) and BMIs from 17.6 to 56.3 kg/m² (mean BMI, 28.5 kg/m² $\pm$ 6.4). Further demographic data is show in Table 2.

For the standard-dose scan, reconstructed with ASIR 30%, the mean CTDI_{vol} was 4.7 mGy $\pm$ 3.3, the mean DLP was 223.6 mGy . cm $\pm$ 162.4, the SSDE 5.3 mGy $\pm$ 2.5, with an effective dose of 3.4 mSv $\pm$ 2.4. For the reduced-dose scan, reconstructed with MBIR, the mean CTDI_{vol} was 2.2 mGy $\pm$ 2.0, the mean DLP was 102.6 mGy . cm $\pm$ 97.0, the SSDE 2.3 mGy $\pm$ 1.6, with an effective dose of 1.5 mSv $\pm$ 1.5. On average, the effective dose was 58.0% $\pm$ 9.5% (range, 34%-84%) less for the reduced-dose scan (Table 3).

The objective measurement of noise showed significant improvement in image quality between the ASIR 30% and MBIR algorithms on the reduced-dose scan (59.9 $\pm$ 14.8 compared with 19.7 $\pm$ 3.9

respectively, a reduction of 67%, $P < 0.001$)(Fig. 1). There was also a significant improvement in noise between the standard-dose ASIR 30% scan and the reduced-dose MBIR scan (40.3 ± 8.3 vs 19.7 ± 3.9 , a reduction of 51%, $P < 0.001$)(Fig. 2). When adjusted for dose, the derived FOM demonstrated significantly lower noise ($P = 0.0001$) on the MBIR scan than both the standard and reduced-dose ASIR scans (Fig. 3).

When assessed qualitatively, no difference in image quality was observed between the standard-dose scan and the reduced-dose scan reconstructed using MBIR (mean score of 3.8 ± 0.6 vs 3.8 ± 0.8 respectively, $P = 0.75$) (Table 4). Image quality for this algorithm was therefore satisfactory overall. However, 12 patients were given a subjective quality score of 2 (*poor*) on the reduced-dose MBIR reconstructed scan. These patients had on average a much lower BMI than our cohort taken as a whole (22.3 compared with 28.5) and therefore received a lower dose (mean CTDI_{vol} $0.71 \text{ mGy} \pm 0.21$, range 0.43-0.98), than the cohort as a whole (CTDI_{vol} $2.2 \text{ mGy} \pm 2.0$). There was a significant difference in subjective image quality between the reduced-dose scan reconstructed using ASIR 30% and both the standard-dose scan and reduced-dose MBIR scan (Table 4). The mean score of 2.8 ± 0.6 for reduced-dose ASIR 30% was below the threshold deemed diagnostically acceptable.

For the primary endpoint (presence of ureteric stone), for each reader, review of the reduced-dose MBIR scan was found to concur perfectly with that reader's review of the standard-dose scan (Table 5). By contrast, the reduced-dose scans reconstructed using ASIR 30% were of reduced accuracy, with a sensitivity of only 0.81 and 0.86 for readers 1 and 2 respectively (Table 5). The readers agreed with the outcome of the standard-dose and MBIR scans for 123 of the 125 patients ($\kappa = 0.98$). Both disagreements came from differing interpretations about whether a branching renal pelvic calculus was obstructing or not, an opinion felt to be subjective across a spectrum of radiologists.

Of the reduced-dose scans, MBIR was more sensitive for renal calculi than ASIR 30% for every size of stone when the data from both readers was combined (Electronic Table 2). MBIR had excellent sensitivity for stones of 3mm (95.7% identified) and performed perfectly for stones above this size. Accuracy dropped off between 2mm and 1mm, where sensitivity fell from 90% to 67.5%. When overall diagnostic accuracy was considered by various size threshold of renal calculi, the MBIR was shown to be very accurate at detecting renal calculi 3mm and above in size, with sensitivity of 95% in one reader and 100% in the other, with a specificity of 100% for both (Table 6). For a threshold of 2mm

accuracy was lower, with a maximum sensitivity of only 91%, and for a threshold of 1mm accuracy was relatively low with maximum sensitivity and specificity of 0.76 and 0.93 respectively. For all size thresholds, MBIR performed at least as well but usually much better than the reduced-dose ASIR scan (Table 6).

Discussion

In this prospective study we have demonstrated that MBIR can safely enable large dose reductions in CT scans for the assessment of urinary tract calculi. Using the parameters described in Table 1 we achieved reductions in the $CTDI_{vol}$ and SSDE of 53% and 57% respectively compared with our department's standard ASIR 30% protocol. Our average doses are similar to those of recent studies investigating dose reduction in CT KUB scans (SSDE of $2.3 \text{ mGy} \pm 1.6$ compared with the $2.2 \text{ mGy} \pm 0.7$ demonstrated by Fontarensky et al.,[17]; DLP of $102.6 \text{ mGy} \cdot \text{cm} \pm 97.0$ compared with $101 \text{ mGy} \cdot \text{cm} \pm 39.0$ in Moore et al.[32]).

When compared with the standard of care, the reduced-dose MBIR scans maintained image quality and demonstrated significant noise reduction. In contrast, the reduced-dose ASIR 30% scan was not acceptable either subjectively or objectively. Whilst there was no significant qualitative difference between the standard and MBIR scans overall, 12 of the scans were rated as unacceptable in image quality by one of the readers. These scans were in a subset of patients with a much lower average BMI than our study population as a whole, and therefore all received very low doses (all below 1.0 mGy). This phenomenon largely results from the use of automatic tube current modulation and is an issue common to both ASIR[33] and MBIR[17] reconstructed scans for renal colic. Our study was designed to reduce the CT dose to as low as was achievable and therefore we expected to produce a handful of scans of unacceptable quality. In future, we plan to implement a scanning protocol using a minimum dose of 1.0 mGy (a DLP of approximately $45 \text{ mGy} \cdot \text{cm}$), a value almost identical to that determined by Fontarensky et al.,[17]. This will be achieved by increasing the minimum mA setting on the automatic exposure control.

Despite the large dose reduction, the reduced-dose MBIR scans performed excellently when used for the diagnosis of an obstructing calculus, demonstrating perfect intra-observer concordance and

almost perfect inter-observer concordance. The reduced-dose ASIR 30% scan performed more poorly, with sensitivity for obstructing uropathy as low as 0.81 for one reader. Therefore, reducing the dose to this level would not be safe diagnostically if only using an ASIR 30% algorithm (Fig 4).

Whilst MBIR has previously been shown to be diagnostically accurate in scans performed for renal colic[17], this is the first publication concerning the accuracy of MBIR for different sizes of renal stones. Our results show that a reduced-dose protocol MBIR CT scan is very sensitive for the detection of renal stones 3mm and larger; sensitivity for stones of 2mm was also high (90%). MBIR surpassed ASIR 30% when used to reconstruct the same reduced-dose scan data, and its sensitivity for smaller stones is better than other reduced-dose techniques[22]. It also far surpasses the accuracy of ultrasound which detects those equal to or less than 4 and 2 mm at a rate of 37% and 28% respectively[34].

It is clear that MBIR can miss small stones, but whether these are clinically significant or not remains uncertain. Whilst there are good guidelines about how to treat different renal calculi according to size[35], there is a lack of consensus regarding what size renal calculi actually require treatment. Our approach has been to analyse the proportion of stones identified above a certain threshold size, and we have concluded that MBIR is very effective at identifying stones 3mm and above (>95% sensitivity). For stones below this threshold, results should be used with caution as small stones may be missed, and small stones that are identified may be a false positive. Caution should also be exercised in very thin patients, due to a reduction in subjective image quality. These reservations notwithstanding, our results suggest a clear role for MBIR in the follow up of renal calculi, especially in young patients for whom reducing the radiation burden is paramount.

There are some limitations to our study. Firstly, it is impossible to completely blind the assessing radiologist to the type of reconstruction algorithm used as the MBIR scans have a characteristic smoothed and regular appearance which is often readily distinguished from an ASIR reconstructed scan (Fig. 2, 4 and 5). Nonetheless, all reconstructed image sets were blinded and randomised. Recall bias was not thought to be a problem, although as described earlier, there was the potential for this. Secondly, we used our department's standard protocol scan as the reference standard rather than any pathological samples. On balance, this was not felt to be detrimental to our conclusions as the unenhanced CT KUB scan is generally accepted as the gold standard of care for the investigation

of urinary tract calculi[18]. Thirdly, MBIR requires a long reconstruction time (approximately 40 minutes for an abdomen and pelvis, although this was not formally measured). This will undoubtedly improve with advances in computing power and may enable it be used in the emergency setting. We have demonstrated an ideal use for it at present: the outpatient follow-up of renal calculi 3mm and above.

In conclusion, we have been able to reduce the dose of CT KUB scans to an extremely low level, with an average reduction of 58% compared with an already low-dose ASIR 30% scan. This was done without any loss in diagnostic accuracy for obstructing calculi and whilst maintaining very high accuracy for renal calculi of 3mm and above.

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Figures

Figure 1

Graph shows quantitative assessment of the noise in each of the reconstructed series. Bar shows mean of the noise with lines representing standard deviation. Noise is significantly lower in the MBIR scan compared with the other two ($P < 0.001$).

Figure 2

CT images of a 54-year-old male with bilateral renal pain (effective diameter 39 cm; BMI, 40.5 kg/m²). A, standard-dose with ASIR 30% reconstruction (CTDI_{vol} 9.6 mGy; DLP 477.3 mGy . cm; size-specific dose estimate (SSDE) 8.7 mGy). B, reduced-dose with MBIR reconstruction (CTDI_{vol} 4.7 mGy; DLP 233.4 mGy . cm; size-specific dose estimate (SSDE) 4.2 mGy). C, reduced-dose with ASIR 30% reconstruction (dose information as for B). Coronal views of normal kidneys bilaterally. Note the smoothed appearance of the MBIR scan (B) with reduced noise compared with both the other scans.

Figure 3

Graph shows image noise figure of merit (FOM - noise adjusted for dose) for each of the reconstructed series. Bar shows mean FOM with lines representing standard deviation. FOM is significantly higher in the MBIR scan compared with the other two ($P < 0.001$).

Figure 4

CT images of a 44-year-old female with left renal colic (effective diameter 26 cm; BMI, 20.9 kg/m²). A and B, standard-dose with ASIR 30% reconstruction (CTDI_{vol} 2.7 mGy; DLP 118.2 mGy . cm; size-specific dose estimate (SSDE) 3.9 mGy). C and D, reduced-dose with MBIR reconstruction (CTDI_{vol} 0.7 mGy; DLP 29.5 mGy . cm; size-specific dose estimate (SSDE) 1.0 mGy). E and F, reduced-dose with ASIR 30% reconstruction (dose information as for C and D). Note the reduced noise on the reduced-dose MBIR scan compared with both the standard and reduced-dose ASIR reconstructions.

Also note the relative ease with which the obstructing left vesico-ureteric junction stone (white arrows) is seen in C and D compared with the other two scans.

Figure 5

CT images of a 41-year-old male with right renal colic (effective diameter 33 cm; BMI, 24.3 kg/m²). A, standard-dose with ASIR 30% reconstruction (CTDI_{vol} 3.4 mGy; DLP 114.8 mGy . cm; size-specific dose estimate (SSDE) 3.8 mGy). B, reduced-dose with MBIR reconstruction (CTDI_{vol} 1.7 mGy; DLP 71.3 mGy . cm; size-specific dose estimate (SSDE) 1.9 mGy). C, reduced-dose with ASIR 30% reconstruction (dose information as for B). Note the reduced noise on the reduced-dose MBIR scan compared with both the standard and reduced-dose ASIR reconstructions. Small non-obstructing stones (white arrows) are straightforward to identify on the MBIR scan (B). Also note the potential for a false-positive diagnosis of small calculus on the ASIR reconstructed reduced-dose scan (C, white arrowhead) due to additional noise.

Table 1 Imaging and reconstruction parameters

Variable	Standard Dose	Reduced Dose
Patient position	Prone	Prone
Coverage	From above kidneys (if visible) or left hemidiaphragm to symphysis pubis on AP CT radiograph	From above kidneys (if visible) or left hemidiaphragm to symphysis pubis on AP CT radiograph
Acquisition mode	Helical	Helical
Detectors	64 x 0.625 mm	64 x 0.625 mm
Field of view	Dependent on body size	Dependent on body size
Kilovolt	120	120
Presence of milliampere (mA) modulation	Yes	Yes
mA range	10-750	10-750
Noise Index	59.51	85
Pitch	1.375	1.375
Rotation time (sec)	0.6	0.6
Reconstruction algorithm	ASIR 30%	ASIR 30% and MBIR
Thickness (mm)	1.25	1.25

Table 2 Population characteristics (n = 125)

Characteristic	Result
No. of men	71 (56.8%)
No. of women	54 (43.2%)
Mean age*	54.4 ± 16.6 (18-88)
Men	55.9 ± 15.9 (24-88)
Women	52.5 ± 17.4 (18-81)
Weight (kg)*	82.7 ± 18.6 (45-146)
Height (cm)*	170.4 ± 10.9 (142-198)
Mean BMI (kg/m2)*	28.5 ± 6.4 (17.6-56.3)
No. of patients with BMI < 18.5: thin/malnutrition	3 (2.4%)
No. of patients with BMI 18.5 - 24.9: normal	34 (27.2%)
No. of patients with BMI 25 - 29.9: overweight	47 (37.6%)
No. of patients with BMI 30 - 34.9: moderate obesity	24 (19.2%)
No. of patients with BMI 35 - 39.9: severe obesity	9 (7.2%)
No. of patients with BMI > 40: morbid obesity	8 (6.4%)
Effective diameter (cm)*	31.4 ± 4.1 (22-45)
Lateral dimension	36.3 ± 4.6 (28-53)
Anterior dimension	27.2 ± 4.2 (17-39)
First occurrence	
Yes	60 (48%)
No	65 (52%)
One occurrence	31 (47.7%)
Two occurrences	13 (20%)
Three occurrences	7 (10.7%)
Four occurrences	6 (9.2%)
Five occurrences	8 (12.3%)
Renal colic	
Yes	103 (82.4%)
No	22 (17.6%)
Side of occurrence	
Right	40 (38.8%)
Left	63 (61.2%)
Urine dip positive	45 (36%)
Blood	40 (32%)
Nitrites	2 (1.6%)
Leukocytes	3 (2.4%)

Unless otherwise indicated, data are the number of patients, and data in parentheses are percentages

* Data are the mean ± standard deviation with range in parentheses

Table 3 Dosimetry data

Parameter	Standard-dose	Reduced-dose	Dose Reduction	P-Value
CTDIvol (mGy)	4.7 ± 3.3	2.2 ± 2.0	58.1 ± 9.5	<0.001
Effective diameter (cm)	31.4 ± 4.1	31.4 ± 4.1		
SSDE (mGy)	5.3 ± 2.5	2.3 ± 1.6	58.1 ± 9.5	<0.001
DLP (mGy.cm)	223.6 ± 162.4	102.6 ± 97.0	58.0 ± 9.5	<0.001
Effective Dose (mSv)	3.4 ± 2.4	1.5 ± 1.5	58.0 ± 9.5	<0.001

Except for the P values, quantitative data are expressed as mean ± standard deviation. Dose reductions are percentages. SSDE = size-specific dose estimate

Table 4 Quantitative and qualitative assessment of the image quality

Parameter	Standard-dose ASIR 30%	Reduced-dose MBIR	Reduced-dose ASIR 30%	P-Value		
				Standard-dose ASIR 30% vs reduced-dose MBIR	Reduced-dose ASIR 30% vs reduced-dose MBIR	Standard-dose ASIR 30% vs reduced-dose ASIR 30%
Quantitative noise assessment (HU)	40.3 ± 8.3	19.7 ± 3.9	59.9 ± 14.8	<0.001	<0.001	<0.001
Figure of merit (FOM) 10-4	2.48 ± 1.09	29.0 ± 20.1	1.12 ± 0.40	0.0001	0.0001	0.0001
Qualitative noise assessment of kidneys, ureters and bladder						
Score of 1 (unacceptable)	0	0	2 (0.8)			
Score of 2 (poor)	2 (0.8)	12 (4.8)	66 (26.4)			
Score of 3 (fair)	66 (26.4)	67 (26.8)	153 (61.2)			
Score of 4 (good)	150 (60.0)	120 (48.0)	28 (11.2)			
Score of 5 (excellent)	30 (12.0)	51 (20.4)	1 (0.4)			
Mean score	3.8 ± 0.6	3.8 ± 0.8	2.8 ± 0.6	0.75	<0.001	<0.001

Data in parentheses are percentages. Except for p-values, quantitative data are expressed as means ± standard deviation and qualitative data are numbers of patients. Image quality was subjectively analysed by both readers so there are 250 total patient scores

Table 5 Accuracy for detection of ureteric calculi

	Reduced-dose MBIR			Reduced-dose ASIR 30%			Inter-observer concordance (κ value)		
	Sens	Spec	AUC	Sens	Spec	AUC	Standard-dose ASIR 30%	Reduced-dose MBIR	Reduced-dose ASIR 30%
Ureteric Calculi							0.98	0.98	0.95
Reader 1 ^a	1.00	1.00	1.00	0.81 (0.58-0.95)	0.99 (0.95-1.00)	0.90 (0.81-0.99)			
Reader 2 ^b	1.00	1.00	1.00	0.86 (0.64-0.97)	1.00	0.93 (0.85-1.00)			

Accuracy of reduced-dose MBIR compared with reduced-dose ASIR 30% reconstruction in the detection of ureteric calculi. In all cases, the obstructing calculus was causing obstructive uropathy. Sens = sensitivity, Spec = specificity, AUC = area under receiver operating characteristic (ROC) curve.

^a Reader 1: 21 positive and 104 negative scans on the standard dose ASIR 30% reconstructions (reference standard). Using reduced dose MBIR, all scans interpreted correctly ($\kappa=1.00$). Using reduced-dose ASIR 30% there were 17 true positives, 4 false negatives and 1 false positive ($\kappa=0.96$).

^b Reader 2: 21 positive and 104 negative scans on the standard dose ASIR 30% reconstructions (reference standard). Using reduced dose MBIR, all scans interpreted correctly ($\kappa=1.00$). Using reduced-dose ASIR 30% there were 18 true positives, 3 false negatives and no false positives ($\kappa=0.98$).

Table 6 Accuracy of reduced-dose CT scans for detection of renal calculi by minimum size

Size threshold of renal calculi		Reduced-dose MBIR		Reduced-dose ASIR	
		Reader 1	Reader 2	Reader 1	Reader 2
≥5mm	Sens	1.00	1.00	1.00	1.00
	Spec	1.00	1.00	1.00	1.00
	AUC	1.00	1.00	1.00	1.00
≥4mm	Sens	1.00	1.00	0.97 (0.85-1.00)	0.97 (0.83-1.00)
	Spec	1.00	1.00	1.00	1.00
	AUC	1.00	1.00	0.99 (0.96-1.00)	0.98 (0.95-1.00)
≥3mm	Sens	1.00	0.95 (0.82-0.99)	0.90 (0.77-0.97)	0.95 (0.82-0.99)
	Spec	1.00	1.00	1.00	1.00
	AUC	1.00	0.97 (0.94-1.00)	0.95 (0.91-1.00)	0.97 (0.94-1.00)
≥2mm	Sens	0.90 (0.79-0.97)	0.91 (0.80-0.98)	0.81 (0.67-0.90)	0.81 (0.67-0.91)
	Spec	1.00	1.00	0.99 (0.93-1.00)	1.00
	AUC	0.95 (0.91-0.99)	0.96 (0.92-1.00)	0.90 (0.84-0.95)	0.90 (0.85-0.96)
≥1mm	Sens	0.78 (0.65-0.88)	0.74 (0.60-0.85)	0.64 (0.50-0.76)	0.57 (0.43-0.71)
	Spec	1.00	0.99 (0.92-1.00)	0.99 (0.92-1.00)	0.97 (0.90-1.00)
	AUC	0.89 (0.84-0.95)	0.86 (0.80-0.92)	0.81 (0.75-0.88)	0.77 (0.70-0.84)

Data is shown for correct detection of all of a patient's renal calculi by various size thresholds.

Sens = sensitivity, Spec = specificity, AUC = area under receiver operating characteristic (ROC) curve.

Values are expressed with 95% confidence intervals in parentheses where appropriate.

Electronic Table 1 Subjective assessment of image quality scale

1	Landmarks were not visible at all (unacceptable)
2	Anatomical structures visible <25% (poor)
3	Anatomical structures visible between 25%-75% (fair)
4	Anatomical structures visible at >75% (good)
5	Anatomical structures visible at 100% (excellent)

Electronic Table 2 Sensitivity of reduced-dose CT scans for renal calculi of various sizes

	Reduced-dose MBIR			Reduced-dose ASIR		
	Reader 1	Reader 2	Reader 1 + 2	Reader 1	Reader 2	Reader 1 + 2
Overall	122/138 (78.2)	138/156 (88.5)	260/294 (88.4)	112/138 (71.8)	119/156 (76.3)	231/294 (78.6)
Size of calculus						
≥5mm	32/32 (100)	35/35 (100)	67/67 (100)	32/32 (100)	35/35 (100)	67/67 (100)
4mm	17/17 (100)	16/16 (100)	33/33 (100)	16/17 (94.1)	15/16 (93.8)	31/33 (93.9)
3mm	25/25 (100)	20/22 (90.9)	45/47 (95.7)	22/25 (88)	21/22 (95.5)	43/47 (91.5)
2mm	26/31 (83.9)	37/39 (94.9)	63/70 (90)	24/31 (77.4)	28/39 (71.8)	52/70 (74.3)
1mm	22/33 (66.7)	30/44 (68.2)	52/77 (67.5)	18/33 (54.5)	20/44 (45.5)	38/77 (49.4)

Data are numbers of calculi, with sensitivity percentages in parentheses.